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|---|---------------|----------------------|---------------------|------------------|
| APPLICATION NO.   | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/550,996  | 09/26/2005    | Zhiwei Zhou          | 10459.204-US        | 1423             |
| 25908   | 7590          | 11/14/2008           | EXAMINER            |                  |
| NOVOZYMES NORTH AMERICA, INC.<br>500 FIFTH AVENUE<br>SUITE 1600<br>NEW YORK, NY 10110 |               |                      | WATTS, JENNA A      |                  |
| ART UNIT  | PAPER NUMBER  |                      |                     |                  |
|   |               | 4132                 |                     |                  |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |
|------------------------------|--------------------------------------|-------------------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/550,996 | <b>Applicant(s)</b><br>ZHOU, ZHIWEI |
|                              | <b>Examiner</b><br>JENNA A. WATTS    | <b>Art Unit</b><br>4132             |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 25 September 2005.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 7-20 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 7-20 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 20080215, 20070501, 20050926

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 7-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding Claims 7-12, it is unclear what the claimed reduction of storage haze in the tea extract is being compared to, for example, an untreated tea extract. Furthermore, it is unclear what it meant by "storage induced haze." Applicant discloses various storage treatments in the instant specification, but there is no categorical definition that explains that "storage induced haze" in the claim language refers to any specific storage treatment regime.

4. Regarding Claims 14 and 15, the phrase "is derivable" is unclear because it could mean that the pectin lyase is able to be derived from the particular fungus claimed, or that the pectin lyase claimed in the instant application is in fact derived from the particular fungus. For the purposes of examination, it will be assumed that the fungal pectin lyase is able to be derived from the particular fungus claimed.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kogya (CN 87103320 A) in view of Kuntz (Food Product Design article), and in further view of Tsai (U.S. Patent No. 4639375).

8. Regarding Claims 7-12, Kogya teaches reducing storage induced sediment/haze formation in a packaged tea extract (Page 1, Paragraph 1), by taking tea extract and combining it with a particular amount of a pectinase enzyme (Page 2, Paragraph 7). Kogya teaches also preparing a control tea product without enzyme added (Page 2, Paragraph 7). The combination of the tea extract and pectinase is then mixed and allowed to stand (Page 2, Paragraph 7). The sediment is then separated by centrifugation and the amount of sediment measured (Page 2, Paragraph 7). The

resulting tea drink is then packaged by loading the tea extract into 180ml flasks and then sterilized (Page 3, Paragraph 6). The filled flasks or bottles are subsequently stored at various temperatures, including room temperature, until any sediment is formed (Page 3, Paragraph 6). Kogya teaches that the drink produced by the method of the invention did not give rise to sediment/haze even after 6 months of storage (Page 3, Paragraph 6), thus the reduction of storage induced sediment/haze formation can be seen as 100%, as compared to the untreated tea product. The storage induced sediment/haze formation would also then be reduced by at least 10%, and at least 50%, 75%, 90%, 95%, 99%, as compared to an untreated tea product that did develop sediment during storage.

9. Kogya does not teach specifically using pectin lyase as the pectinase enzyme in the reaction.

10. Kuntz teaches that both tea and fruit juices contain insoluble solids that prevent the clarity of the beverages. Kuntz further teaches that in the case of fruit juice, the cell walls of fruits consist of pectin, among other compounds. Kuntz teaches that adding pectin lyase enzymes to break down these pectin structures make it possible to extract a larger amount of juice and to produce a clear juice (Page 3, Paragraph 12).

11. Kogya in view of Kuntz do not specifically state the presence of pectin in tea.

12. Tsai teaches a method of clarifying tea with enzymes including pectinases (Column 2, lines 20-25). Tsai further teaches that pectin, among other compounds, are constituents of tea cell-walls and that pectinases are cell-wall-digesting enzymes that break down one or more tea cell-wall constituents into simpler materials, a process

which reduces the structural integrity and increases the permeability of the cell wall  
(Column 3, lines 1-10).

13. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the pectinase used in the experiment taught by Kogya with pectin lyase as taught by Kuntz because Kogya teaches using a pectinase enzyme to clarify tea, and both Kuntz and Tsai teach that fruit juice and tea suffer from a similar problem of needing clarification and teach clarifying with enzymes that break down pectin in order to produce a clear product. In this light, one of ordinary skill would have been motivated to look to the fruit juice industry to solve this problem, particularly since Kuntz teaches that pectin lyase is a type of pectinase that has been found to successfully clarify fruit juice (Page 4, Paragraph 4). Furthermore, Kuntz teaches that enzymes used in fruit juice processing have a lower pH optima and have to be acid-tolerant since most juices have a pH between 3 and 4 (Page 5, Paragraph 6). Kogya teaches that the optimum pH of the enzymatic tea clarification reaction is at pH 3-8, and so one of ordinary skill in the art would have expected that pectin lyase would also be suitable for clarifying tea.

14. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kogya (CN 87103320 A) in view of Kuntz (Food Product Design) and Tsai (U.S. Patent No. 4, 639375), and in further view of Bida (Advance in Bioengineering).

15. Kogya in view of Kuntz and Tsai are relied upon as above in the rejection of Claim 7.

16. Kogya in view of Kuntz and Tsai do not specifically teach the pectin lyase being a fungal pectin lyase.
17. Regarding Claim 13, Bida teaches that the fungal enzymes that break down pectic substances are mainly polygalacturonase and pectin lyase (Page 1, Paragraph 3). Regarding Claims 14 and 15, Bida further teaches that pectin lyase is mainly produced by *Aspergillus* and other organisms, and has been cloned from *Aspergillus niger*.
18. It would have been obvious to one of ordinary skill in the art at the time of the invention for the pectin lyase taught by Kogya in view of Kuntz and Tsai to be of a fungal origin and derivable from *Aspergillus niger* because Bida teaches that the fungus *Aspergillus niger* is the main source of pectin lyase, thus it would have been the most reliable choice for the source of the enzyme for commercial processing.
19. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kogya (CN 87103320 A) in view of Kuntz (Food Product Design) and Tsai (U.S. Patent No. 4, 639, 375), and in further view of Sanderson (U.S. Patent No. 3, 787, 582).
20. Kogya in view of Kuntz and Tsai are relied upon as above in the rejection of Claim 7.
21. Regarding Claims 16-19, Kogya in view of Kuntz and Tsai do not teach the specific ranges as claimed of pectin lyase: from 0.1 to 1,000,000 UPTE per liter of the tea extract, from 1 to 100,000 UPTE per liter, from 10 to 10,000 UPTE per liter, and from 1,000 to 8,000 UPTE per liter.

22. Sanderson teaches using pectinase for preparing high bulk density tea powder with improved clarity (Column 1, Lines 21-26) and teaches that the percent of the pectinase enzyme preparation that is added to the tea extract is critical in view of the fact that too little unduly prolongs the reaction, while the use of excessive amount creates a haze problem of its own.

23. Therefore, the exact concentration of the pectin lyase enzyme is deemed to be a result effective variable with regard to the clarity or haze reduction of the tea. It would require routine experimentation to determine the optimum value of a result effective variable, such as the concentration of the pectin lyase enzyme, in the absence of a showing of criticality in the claimed concentration of the pectin lyase enzyme. *In re Boesch*, 205 USPQ 215 (CCPA 1980), *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). One of ordinary skill in the art would have been motivated by Sanderson to optimize the concentration of the pectin lyase enzyme in order to ensure that the clarification of the tea is successful for long-term storage of the tea product in a commercial setting. One would have been motivated to optimize the concentration in order to prevent incomplete clarification of the tea, or to cause further hazing issues, as taught by Sanderson, if the enzyme concentration was too high.

24. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kogya (CN 87103320 A) in view of Kuntz (Food Product Design) and Tsai (U.S. Patent No. 4, 639, 375), and in further view of Alkorta (Enzyme and Microbial Technology).

25. Kogya in view of Kuntz and Tsai are relied upon as above for the rejection of Claim 7.

26. Kogya in view of Kuntz and Tsai do not teach the immobilization of the pectin lyase on a solid support.

27. Alkorta teaches clarifying fruit juice using an pectin lyase immobilized to Nylon (See Abstract of article). Alkorta teaches that the immobilization of pectic enzymes such as pectin lyase appear to offer several advantages in comparison with processes where soluble enzymes are used for the clarification of fruit juices (Column 2, Paragraph 2). In particular, Alkorta teaches that the immobilized pectin lyase was more stable at lower pH's than the soluble enzyme, that it caused a marked increase in the thermal stability of the enzyme, that it showed extraordinary stability during storage at 4 °C, and, lastly, that no loss of activity was observed when the immobilized enzyme was used for 12 consecutive cycles of operation (See abstract of article).

28. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the pectin lyase taught by Kogya in view of Kuntz and Tsai with the immobilized pectin lyase taught by Alkorta in order to increase the economization and productivity of the enzymatic clarification of the tea. One of ordinary skill in the art would have been motivated to use the immobilized pectin lyase in order to maximize the use of the enzyme with multiple batches of tea. Furthermore, because the immobilization increases the thermal stability of the enzyme, it would be possible for the clarification reaction to occur at a higher temperature, and thus at a faster rate.

***Conclusion***

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNA A. WATTS whose telephone number is (571)270-7368. The examiner can normally be reached on Monday through Thursday from 9am to 5pm.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Lavilla, can be reached on (571) 272-1539. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JENNA A. WATTS/  
Examiner, Art Unit 4132  
November 10, 2008

/Michael La Villa/  
Michael La Villa  
Supervisory Patent Examiner, Art Unit 4132  
10 November 2008